EXHIBIT 20

EXHIBIT C

Notice of FDA Warning regarding the use of vaginal mesh:

The U.S. Food and Drug Administration (FDA) has issued several safety communications about the use of mesh for pelvic organ prolapse (POP). However, this AUA guideline reviews the current literature regarding SUI alone, and covers neither POP nor mini-incision slings. The FDA warning does not apply to biologicals used in POP. Based on continuing adverse event reports that have been received by the FDA since their initial warning in 2008, the FDA has stated that serious complications associated with surgical mesh in transvaginal POP repairs are not rare.

The AUA will continue to monitor the FDA's alerts and notices and will update the guideline as additional warnings or alerts regarding this device are issued. Informed consent requires that patients be advised of the risks of vaginal mesh.

The FDA will provide updates on its Web page:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm.

Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update

American Urological Association
Education and Research, Inc.

Female Stress Urinary Incontinence Guideline Update Panel:

Rodney A. Appell, MD, Chair
Roger R, Dmochowski, MD, Facilitator
Jerry M. Blaivas, MD
E. Ann Gormley, MD
Mickey M. Karram, MD
Saad Juma, MD
Deborah J. Lightner, MD
Karl M. Luber, MD
Eric Scott Rovner, MD
David R. Staskin, MD
J. Christian Winters, MD

Consultants:

Hanan S. Bell, PhD
Patrick M. Florer
Linda Whetter, DVM, PhD

AUA Staff:

Heddy Hubbard, PhD, MPH
Edith Budd
Suzanne Pope, MBA
Michael Folmer
Katherine Moore
Cynthia Janus, MLS
Kadiatu Kebe

Rodney Alan Appell, MD, FACS

1948 – 2009

Dr. Rodney Appell served as Professor of Urology and Gynecology and Chief, Division of Voiding Dysfunction and Female Urology, at Baylor College of Medicine and held a large private practice in Houston, Texas. He was a highly respected surgeon in female urology and an active member of the American Urological Association (AUA), serving on the Practice Guidelines Committee and the Special Women's Issues in Urology Committee.

At the time of his death, he was Chair of the expert Panel that developed the Stress Urinary Incontinence Clinical Guideline. Directing the Panel members through the painstaking and analytical challenge of systematically reviewing clinical studies so that appropriate practice recommendations could be made was an undertaking at which Dr. Appell excelled. In remembering him, the current guideline Chair, Roger R. Dmochowski, M.D., Professor, Dept of Urologic Surgery, Vanderbilt University, speaking for the Panel, remarked that "Rodney will be missed by us all. His vision of mentorship was the inspiration for a whole generation of residents and fellows. Those of us who knew him will treasure the memory of his unique insight and clinical expertise."

After receiving his medical degree from Jefferson Medical College, Dr. Appell completed his surgical residency at George Washington University Medical Center and residency in urology at Yale University. Since that time and until his death he achieved extensive accomplishments in his field through research, clinical practice, and education activities. Consistently included in the publication *The Best Doctors in America*, Dr. Appell published over 100 full papers or editorials in peer-reviewed journals, authored several book chapters, was invited to participate in more than 200 lectureships and symposia, and delivered over 800 educational talks and presentations both across the United States and around the world. He served on the editorial boards of many publications, including the AUA Journal of Urology. In February 2008, he was awarded the Lifetime Achievement Award by the Society for Urodynamics and Female Urology and was named Continence Care Champion by the National Association for Continence.

Dr. Appell's leadership and expertise will be missed by all who knew him. The Stress Urinary Incontinence Guidelines Panel dedicates this Clinical Guideline to his memory.

Table of Contents

Recommendation: Surgical procedures for SUI and prolapse may be safely performed concomitantly in appropriately selected women. Tensioning of any sling should not be performed until prolapse surgery is completed.

[Based on Panel consensus]

Recommendations for Future Research and Reporting

Recommendations to Editors and Reviewers

Although more than a decade has passed since the recommendations for improving the quality of data from clinical trials and studies were proposed by Leach et al.,[4] very little progress has been made by editors and reviewers in instituting these recommendations.[27] Furthermore, the FDA has not altered the approval process as discussed below. Thus, again, the Panel members were extremely disappointed in data available for meta-analysis. In addition to the specific data outlined by Leach et al.[4] in the original Panel report, editors and their reviewers should require:

- Defined outcome measures obtained preoperatively and followed postoperatively
  - validated questionnaires
  - bladder diary
  - pad test
  - exam with full bladder
- A minimum follow-up of at least 12 months of all surgically treated patients for reporting of efficacy data
- A grading of the degree of prolapse (anterior, posterior, apical) as determined by preoperative pelvic examination recorded on all patients

For adverse event data, complications should be categorized as occurring intraoperatively or postoperatively. It is essential to report the following adverse event data:

- Overactive bladder symptoms, which should include persistent overactivity (already present preoperatively) or de novo overactivity (occurring as a complication of the surgery)
- Persistent or de novo other lower urinary tract symptoms
- Urinary retention of greater than four weeks and/or requiring intervention
- Infection (reported as wound infection, vaginal infection, symptomatic urinary tract infection, pelvic abscess, etc.)
- Fever (sepsis)
- Postoperative pain, bleeding, thromboembolus formation (lower extremity, pulmonary or other)
- Lower urinary tract or vaginal injury or erosion
- Refractory pain
- Other serious complications, including vascular or bowel injury, death

The profession at large and the individual physician should insure the safety and efficacy of any new device or sling. If safety and efficacy has not been shown with reasonable certainty, the new treatment should only be performed as part of clinical research studies and/or with informed consent recognizing that safety and/or efficacy has not been demonstrated.